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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/628,792	
	Filing Date	07/28/2003	
	First Named Inventor	Jon A. Wolff	
	Art Unit		
	Examiner Name		
Total Number of Pages in This Submission	>100	Attorney Docket Number	Mirus.040.01

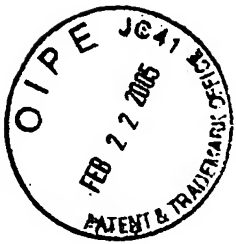
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/628,792
Applicants : Jon A. Wolff
Filed : 07/28/2003
Art Unit :
Examiner :

Docket No. : Mirus.040.01

For: **Delivery of Molecules and Complexes to Mammalian Cells in Vivo**

Commissioner of Patents
PO Box 1450
Alexandria, VA 2231-1450

INFORMATIONAL STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449.

<u>US patent</u>		
<u>Patent No.</u>	<u>Applicant</u>	<u>Issue date</u>
US-5,521,291	Curiel, David T.	05/28/1996
US-5,580,859	Felgner, Philip L.	12/03/1996
US-5,583,020	Sullivan, Sean	12/10/1996
US-5,598,531	Nabel, Elizabeth	12/16/1997
US-5,744,335	Wolff, Jon A. et al.	04/28/1998
US-5,922,687	Mann, Michael J.	07/13/1999
US-6,180,784	Wolff, Jon A. et al.	01/30/2001
US-2003-0143204	Lewis, David et al.	07/03/2003
US-2003-0125281	Lewis, David et al.	07/03/2003

Foreign Patent Publications

<u>Publication No.</u>	<u>Applicant</u>	<u>Publication date</u>
WO 99/31982 Stedman	07/01/1999	

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2. Boulikas, Teni, "Gene Therapy to Human Diseases: Ex Vivo and In Vivo Studies (Review)." International Journal of Oncology; 1996; vol. 9; pp. 1239-1251.
3. Budker V et al. "Naked DNA delivered intraportally expresses efficiently in hepatocytes." Gene Therapy; 1996 Vol. 3 No. 7 pp. 593-598.
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5. Chapman G et al. "Gene transfer into coronary arteries of intact animals with a percutaneous balloon catheter," Circ. Res; 1992 Vol. 71 pp. 27-33
6. Chowdhury JR et al. "Long-term improvement of hypercholesterolemia after ex vivo gene therapy in LDLR-deficient rabbits," Science; 1991 Vol. 254 pp. 1802-1805
7. Coll JL et al. "In Vivo Delivery to Tumors of DNA Complexed With Linear Polyethylenimine." Human Gene Therapy; 1999 Vol. 10 pp. 1659-1666.
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9. French, Brent A., Et al., "Cellular and Molecular Cardiology: Percutaneous Transluminal In Vivo Gene Transfer by Recombinant Adenovirus in Normal Porcine Coronary Arteries, Atherosclerotic Arteries, and Two Models of Coronary Restenosis." Circulation; November 1994; vol. 90(5); pp. 2402-2413.
10. Greelish JP et al. "Stable restoration of the sarcoglycan complex in dystrophic muscle perfused with histamine and a recombinant adeno-associated viral vector." Nature; 1999 Vol. 5 no. 4 pp. 439-443
11. Hengge UR et al. "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," Nature Genetics; 1995 Vol. 10 pp. 161-166

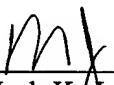
12. Hickman MA et al. "Gene expression following direct injection of DNA into liver," *Human Gene Therapy*; 1994 Vol. 5 pp. 1477-1483
13. Jaffe HA et al. "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," *Nat. Genet*; 1992 Vol. 1 pp. 372-378
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15. Kaneda Y et al. "Increased expression of DNA cointroduced with nuclear protein in adult rat liver," *Science*; 1989 Vol. 243 pp. 375-378
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27. Rekhter, Mark D. MD, PhD, Et al., "Graft Permeabilization Facilitates Gene Therapy of Transplant Arteriosclerosis in a Rabbit Model." Circulation; September 29, 1998; vol. 98(13); pp. 1335-1341.
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31. Sikes M et al. "In vivo gene transfer into rabbit thyroid follicular cells by direct DNA injection," Hum. Gene Ther; 1994 Vol. 5 p. 837-844
32. Simari, Robert D., Et al., "Regulation of Cellular Proliferation and Intimal Formation Following Balloon Injury in Atherosclerotic Rabbit Arteries." Gene Therapy for Atherosclerotic Arteries; J. Clin. Invest.; July 1996; vol. 98, no. 1; pp. 225-235.
33. Soriano P et al. "Targeted and nontargeted liposomes for in vivo transfer to rat liver cells of a plasmid containing the preproinsulin I gene," PNAS; 1983 Vol. 80 pp. 7128-7131
34. Stratford-Perricaudet LD et al. "Evaluation of the transfer and expression in mice of an enzyme-encoding gene using a human adenovirus vector," Hum. Gene Ther; 1990 Vol. 1 pp. 241-256
35. Vile RG et al. "In vitro and in vivo targeting of gene expression to melanoma cells," Cancer Res; 1993 Vol. 53 pp. 962-967
36. Von Der Leyen, Heiko, E., Et al., "A Pressure-Mediated Nonviral Method For Efficient Arterial Gene and Oligonucleotide Transfer." Human Gene Therapy 1999 Vol. 10 pp. 2355-2364.
37. Wolff JA et al. "Direct gene transfer into mouse muscle in vivo," Science; 1990 Vol. 247 pp. 1465-1468
38. Wolff JA et al. "Expression of retrovirally transduced genes in primary cultures of adult rat hepatocytes," Proc Natl Acad Sci USA; 1987 Vol. 84 pp. 3344-3348

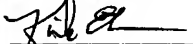
39. Zhang G et al. "Efficient Expression of Naked DNA Delivered Intraarterially to Limb Muscles of Nonhuman Primates." Hum Gene Ther; 2001 Vol. 12 pp. 427-438.
40. Zhang G et al. "Expression of Naked Plasmid DNA Injected into the Afferent and Efferent Vessels of Rodent and Dog Livers." Human Gene Therapy; 1997 Vol. 8 pp. 1763-1772.
41. Zhang G et al. "High Levels of Foreign Gene Expression in Hepatocytes after Tail Vein Injections of Naked Plasmid DNA." Hum Gene Ther; 1999 Vol. 10 pp. 1735-1737.
42. Zhu N et al. "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice." Science; 1993 Vol. 261 pp. 209-211.

Applicant respectfully requests that these publications be expressly considered during the prosecution of this application and made of record herein and appear among the 'References Cited' on any patent to issue herefrom.

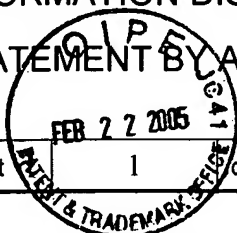
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Kirk Ekena

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/628,792
		Filing Date	07/28/2003
		First Named Inventor	Jon A. Wolff
		Art Unit	
		Examiner Name	
Sheet 1 of 3		Attorney Docket Number	Mirus.040.01



U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number – Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,521,291	05/28/1996	Curiel, David T.	
		US-5,580,859	12/03/1996	Felgner, Philip L.	
		US-5,583,020	12/10/1996	Sullivan, Sean	
		US-5,598,531	12/16/1997	Nabel, Elizabeth	
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		US-2003-0143204	07/03/2003	Lewis, David et al.	
		US-2003-0125281	07/03/2003	Lewis, David et al.	

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner Initials	Document Number	Publication Date	Country or Patent Office	Class	Sub Class	Transl.	
	WO 99/31982	07/01/99	US			yes	no

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.		T
		Acsadi Get al. "Direct gene transfer and expression into rat heart in vivo" The New Biologist; 1991 Vol. 3 no. 1 pp. 71-81	
		Boulikas, Teni, "Gene Therapy to Human Diseases: Ex Vivo and In Vivo Studies (Review)." International Journal of Oncology; 1996; vol. 9; pp. 1239-1251.	
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	Zhu N et al. "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice." Science; 1993 Vol. 261 pp. 209-211.	

Examiner Signature		Date Considered	
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